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| 10/775,961 | 02/10/2004 | Paul J. Thompson | 23,369-162 | 1606 |
| 23452 . 7590 11/05/2004 | | EXAMINER | | |
| PATENT DEPARTMENT | | | PREBILIC, PAUL B | |
| LARKIN, HO | FFMAN, DALY & LINDG | REN, LTD. | | |
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| BLOOMINGT | ON, MN 55431 | | - 1- 1 | |

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Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary Examiner | 1 | Application No. | Applicant(s) | | | | |
|---|---|---|--|--|--|--|--|
| Paul B. Prebilic The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. If No period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 10 February 2004. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 60-77 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) 60-77 is/are rejected. | Office Action Commons | 10/775,961 | THOMPSON, PAUL J. | | | | |
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| 6)⊠ Claim(s) <u>60-77</u> is/are rejected. | | | | | | | |
| ,— | 5) Claim(s) is/are allowed. | | | | | | |
| | 6)⊠ Claim(s) <u>60-77</u> is/are rejected. | | | | | | |
| 7) Claim(s) is/are objected to. | 7) Claim(s) is/are objected to. | | | | | | |
| 8) Claim(s) are subject to restriction and/or election requirement. | 8) Claim(s) are subject to restriction and/or | election requirement. | | | | | |
| Application Papers | Application Papers | | | | | | |
| 9) The specification is objected to by the Examiner. | 9) The specification is objected to by the Examiner | ſ. | | | | | |
| 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. | | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | Applicant may not request that any objection to the c | frawing(s) be held in abeyance. See | e 37 CFR 1.85(a). | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | 11)☐ The oath or declaration is objected to by the Ex | aminer. Note the attached Office | Action or form PTO-152. | | | | |
| Priority under 35 U.S.C. § 119 | Priority under 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: | | | | | | | |
| 1. ☐ Certified copies of the priority documents have been received. | | | | | | | |
| Certified copies of the priority documents have been received in Application No | | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | | | |
| application from the International Bureau (PCT Rule 17.2(a)). | | | | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | |
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| Attachment(s) | | | | | | | |
| 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s)/Mail Date | | | | | | | |
| 2) Notice of Draitsperson's Patent Drawing Review (PTO-946) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 5) Notice of Informal Patent Application (PTO-152) 6) Other: | 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) 🔲 Notice of Informal P | | | | | |

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

'A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 61 and 69 recites the broad recitation body fluids, and the claim also recites blood which is the narrower statement of the range/limitation; see the last lines of these claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 60-77 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6, 11-13, and 15-22 of U.S. Patent No. 6,689,162. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent "anticipate" the application claims. Accordingly, application claims are not patentably distinct from patent claims. Thus it is apparent that the more specific patent claims encompass the application claims. Following the rationale in In re Goodman cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

Claims 61, 62, 64, and 67 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 6, and 8 of U.S. Patent No. 6,342,068. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent "anticipate" the application claims. Accordingly, application claims are not patentably distinct from patent claims. Thus it is apparent that the more specific patent claims encompass the application claims. Following the rationale in In re Goodman cited in the preceding

paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

Claims 61 and 66 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,019,768. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent "anticipate" the application claims. Accordingly, application claims are not patentably distinct from patent claims. Thus it is apparent that the more specific patent claims encompass the application claims. Following the rationale in In re Goodman cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

Claims61, 62, 64, and 67 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 6, and 8 of U.S. Patent No. 6,592,617. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent "anticipate" the application claims. Accordingly, application claims are not patentably distinct from patent claims. Thus it is apparent that the more specific patent claims encompass the application claims. Following the rationale in In re Goodman cited in the preceding

paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

Claims 61, 62, 64, and 67 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 54, 55, 68, 73, 74, 75, 83, 90, 92, and 93 of copending Application No. 10/619,888.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are clearly obvious over the patented claims such that they are read on thereby.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections Based Upon Prior Art

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 60-64, 66-73, and 75-77 are rejected under 35 U.S.C. 102(b) as being anticipated by Silvestrini et al (US 4,834,755). Silvestrini et al anticipates the claim language wherein there are distinct fiber sets which can be metal (stainless steel) and where the selected orientations can be of the strands of the braided device in relaxed state and not necessarily the strands before interbraiding; see column 5, lines 7-11. The fibers are inherently both elastic and plastic in that they are not perfectly rigid. Furthermore, fiber sets 11 and 13 are in a helical shape and together impart the shape to the device to the extent that this language can be given patentable weight; see Figures 1 and 2. In addition, the curved nominal shapes as claimed are not positively required such that even fiber set 9 meets the claim language when it is viewed as imparting a tubular profile to the prosthesis.

With regard to claim 61 and 69, the claimed textile strands can be the longitudinal or warp direction set 9 that is more elastic or compliant than the helical fibers; see column 4, lines 44-47. They inherently would prevent leakage of body fluids as compared to a structure where they were not present because they fill the interstices of the structure.

Regarding claim 66, Examples 1 and 3 disclose the use of a monofilament fiber set for fiber set 9. When one considers the claimed structural strands to be those of fiber set 9 and one of set 11 or 13, then the claim language is fully met.

Regarding claim 67, Applicant is directed to Examples 1 and 3 that disclose the use of multifilament PET fibers.

Claims 65 and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silvestrini (US 4,834,755) in view of Mikhail (US 5,282,867). Silvestrini meets the claim language except for the use of cobalt-chrome-molybdenum alloy for the structural strands. However, Mikhail teaches that is was known to make similar implants, including artificial ligament prostheses, out of this alloy; see column 4, lines 25-33. Therefore, it is the Examiner's position that it would have been prima fascia obvious to make sets 11 or 13 of Silvestrini out of this alloy for the same reasons that Mikhail uses such and because of its higher strength-to-weight ratio as compared to stainless steel.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott Corrine can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Paul Prebilic

Primary Examiner

Art Unit 3738